PUBLIC CHAPTER NO. 224

SENATE BILL NO. 1112

By McNally, Burks, Marrero, Bunch, Williams, Raymond Finney

Substituted for: House Bill No. 1343

By Overbey, Shepard, Matheny, Hackworth, Sargent, Eldridge

AN ACT to amend Tennessee Code Annotated, Title 56 and Title 63, relative to pharmacy benefits managers.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, is amended by adding the following as a new part to be appropriately designated:

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Pharmacy benefits managers shall, and contracts for pharmacy benefits management must, comply with the requirements of this part.

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As used in this part, unless the context otherwise requires:

- (1) "Covered entity" means a health insurance issuer, managed health insurance issuer as defined in § 56-32-228(a), nonprofit hospital, medication service organization, insurer, health coverage plan, health maintenance organization licensed to practice pursuant to Title 56, a health program administered by the state or its political subdivisions including the TennCare programs administered pursuant to the waivers approved by the United States Department of Health and Human Services, nonprofit insurance companies, prepaid plans, self-insured entities, and all other corporations, entities or persons, or an employer, labor union, or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, or other long-term care;
- (2) "Pharmacy benefits manager" means a person, business or other entity and any wholly or partially owned subsidiary of such entity, that administers the medication and/or device portion of pharmacy benefits coverage provided by a covered entity. "Pharmacy benefits manager" includes, but is not

limited to, a health insurance issuer, managed health insurance issuer as defined in § 56-32-228(a), nonprofit hospital, medication service organization, insurer, health coverage plan, health maintenance organization licensed to practice pursuant to Title 56, a health program administered by the state or its political subdivisions including the TennCare programs administered pursuant to the waivers approved by the United States Department of Health and Human Services, nonprofit insurance companies, prepaid plans, self-insured entities, and all other corporations, entities or persons acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes, but is not limited to, a mail order pharmacy; and

(3) "Pharmacy" and "Pharmacist" have the same meanings as those terms are defined in § 63-10-204.

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- (a) When an audit of records of a pharmacist or pharmacy is conducted by a covered entity, a pharmacy benefits manager, the state or its political subdivisions, or any other entity representing the same, it shall be conducted in the following manner:
 - (1) Written notice shall be given to the pharmacy or pharmacist at least two (2) weeks prior to conducting the initial onsite audit for each audit cycle;
 - (2) Any audit performed under this section which involves clinical or professional judgment must be conducted in consultation with a pharmacist who has knowledge of the provisions of the Tennessee Pharmacy Practice Act under Title 63, Chapter 10;
 - (3) Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record may not, in and of itself, constitute fraud; however, such claims may be subject to recoupment. Notwithstanding any other provision of law to the contrary, no such claim shall be subject to criminal penalties without proof of intent to commit fraud;
 - (4) A pharmacy or pharmacist may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medical supplies written or transmitted by any means of communication for purposes of validating pharmacy records with respect to orders or refills of a legend or narcotic drug;
 - (5) A finding of overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar

drugs; however, recoupment of claims must be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy or pharmacist;

- (6) Each pharmacy or pharmacist shall be audited under the standards and parameters as other similarly situated pharmacies or pharmacists audited by a covered entity, a pharmacy benefits manager, the state or its political subdivisions, or any other entity representing the same;
- (7) A pharmacy or pharmacist shall be allowed the length of time described in the pharmacy's or pharmacist's contract or provider manual, whichever is applicable, which shall not be less than thirty (30) days, following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit. If the pharmacy's or pharmacist's contract or provider manual does not specify the allowed length of time for the pharmacy or pharmacist to address any discrepancy found in the audit following receipt of the preliminary report, such pharmacy or pharmacist shall be allowed at least thirty (30) days following receipt of the preliminary audit report to respond and produce documentation;
- (8) The period covered by an audit may not exceed two (2) years from the date the claim was submitted to or adjudicated by a covered entity, a pharmacy benefits manager, the state or its political subdivisions, or any other entity representing the same, except this provision will not apply where a longer period is required by any federal rule or law;
- (9) An audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time unless otherwise consented to by the pharmacy or pharmacist;
- (10) The preliminary audit report must be delivered to the pharmacy or pharmacist within one hundred twenty (120) days after conclusion of the audit. A final audit report shall be delivered to the pharmacy or pharmacist within six (6) months after receipt of the preliminary audit report or final appeal, whichever is later; and
- (11) Notwithstanding any other provision of law to the contrary, any audit of a pharmacy or pharmacist shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.
- (b) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeal process as set forth in subsection (c) of this section.

(c) Each pharmacy benefits manager, as defined in 56-__-(a)(2), conducting an audit shall establish an appeals process under which a pharmacy or pharmacist may appeal an unfavorable preliminary audit report to the pharmacy benefits manager on whose behalf the audit was conducted. The pharmacy benefits manager conducting any audit shall provide to the pharmacy or pharmacist, before or at the time of delivery of the preliminary audit report a written explanation of the appeals process, including the name, address and telephone number of the person to whom an appeal should be addressed. If, following the appeal, it is determined that an unfavorable audit report or any portion thereof is unsubstantiated, the audit report or such portion shall be dismissed without the necessity of further proceedings.

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- (a) Reimbursement by a pharmacy benefits manager under a contract to a pharmacist or pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the pharmacy benefits manager or its agent.
- (b) For purposes of compliance with this section, pharmacy benefits managers shall be required to update the nationally recognized reference prices or amounts used for calculation of reimbursement for prescription drugs and other products and supplies no less than every three (3) business days.

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No contract entered into or amended on or after the effective date of this act shall contain provisions in violation of this act.

SECTION 2. If any provision of this act or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

SECTION 3. This act shall take effect July 1, 2007, the public welfare requiring it.

PASSED: May 9, 2007

RON RAMSEY SPEAKER OF THE SENATE

JIMM NAIFEH, SPEAKER HOUSE OF REPRESENTATIVES

APPROVED this 24th day of May 2007

PHIL BREDESEN, GOVERNOR